

**Labelling and Packaging of Cough and Cold Medicines
Stakeholder and Public Consultation October - December 2009
Submission received from The Society of Hospital Pharmacists of Australia**

The Society of Hospital Pharmacists of Australia (SHPA) generally supports the proposed changes to the availability, labelling, packaging and scheduling of cough and cold medicines for use in children.

Unfortunately, SHPA was not included on the consultation list, so this came to our attention in the past few weeks, so it is hoped that the submission will still be accepted even though it has missed the official closing date.

SHPA has a Paediatric Pharmacy Committee of Speciality Practice (COSP) which assists SHPA to comment on government policies and to make submissions. SHPA also has a representative on the Australian Government's Paediatric Medicines Advisory Group. We would welcome opportunity to comment on any subsequent consultations.

In this case the following brief comments or observations are offered.

Recommendation 2) Packaging

Child resistant closures should be mandated. Our advice is that most issues with cough and cold remedies in children appear to be around accidental poisonings.

Recommendation 3) Scheduling

A change in scheduling to S3 would be warranted. It is not clear that a change in scheduling to S4 for under 6's and S3 for over 6's is workable and SHPA would support S3 for all. It may be that parents may just say it is for on over 6 year old even if for an under 6 to avoid the need for a prescription.

Recommendation 4) Public awareness

The need for public education / awareness will be very important. Without this practice will not change. SHPA's major concern with the changes is that parents will give inappropriate solutions that are no longer labelled for use in a particular age group which could potentially lead to more problems than the current situation. Removing parents' access to products may well lead them to seek out other remedies for which there is also no evidence and with their own set of inherent risks.

The support of community pharmacists for the changes will also be a key success factor. They will need to have a good understanding of the reasons why these changes are being proposed so that they can reinforce the message to parents.

SHPA considers that the first recommendation will cause the most difficulties.

Recommendation 1) Safety, efficacy and availability

This all depends on how pragmatic the policy should be. It may be easy to say if there is no evidence then they shouldn't be available. However in a paediatric environment there are a range of therapies for which there is very limited if any evidence and yet they continue to be used routinely in practice.

This is not to say that they are ineffective but more that the studies to support this use have not been done and unfortunately for many drugs never will be. It then comes down to assessment of risk with the current alternatives.

SHPA suggests that a rationalisation of what is available is important. The combination products and the illogical combinations should be addressed particularly those that contain paracetamol in combination because of the risks with therapeutic overdoses with the use of more than one paracetamol containing preparation at the same time.

If there is to be a removal/reduced access of preparations there needs to be the provision of information about the suitable alternatives /practices – even if it is to say 'use simple linctus' – for its demulcent effect / no adverse effects, honey lemon, lots of fluids etc. The current culture is that parents will want to give something to their children to alleviate symptoms of coughs and colds and it would be naïve to think that changing the recommendations will stop this practice.

Finally, it may be worthwhile to consider what the hospitals, particularly the main paediatric hospitals supply in terms of cough / cold remedies for children. These centres are seen as the barometer of good clinical practice, set the scene for what should be used and are the place where many GPs will receive their paediatric training and where 'practices' are ingrained.